

REMARKS

Claims 1-32 are pending in this application. Claims 1-26 and 29-32 were rejected under 35 U.S.C. § 103. Claims 27 and 28 were objected to as being dependent on a rejected claim.

Claims 7, 26, 31, and 32 have herein been amended to correct typographical errors without prejudice or disclaimer of any previously claimed subject matter. Applicants respectfully request entry of this amendment under 37 C.F.R. §1.116(b). With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed herein, thereby placing this case into condition for allowance.

Rejection under 35 U.S.C. §103

Claims 1-26 and 29-32 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Stewart *et al.* (WO 98/34644, "Stewart"). Applicants respectfully traverse this rejection.

A *prima facie* case of obviousness requires the satisfaction of three requirements. First, as in this case only a single, non-anticipatory document is cited, the reference must suggest all of the claim limitations. Second, the reference must provide a suggestion or motivation to modify the teachings either in the reference itself or in the knowledge generally available to one of ordinary skill in the art. Third, the reference must provide a reasonable expectation of success. MPEP §2143. More specifically, the obviousness analysis under 35 U.S.C. §103 requires the consideration of the scope and content of the prior art, the level of skill in the relevant art, and the differences between the prior art and the claimed subject matter. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Critical elements of the invention as a whole which clearly distinguish the entire invention from the prior art references cannot be ignored. *Panduit Corp. v. Dennison Manufacturing Co.*, 1

USPQ2d 1593, 1597 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987). The fact that a disclosure can be modified is insufficient to establish *prima facie* obviousness in the absence of a suggestion or motivation to make such a modification. MPEP §2142.01. Simply stated, the suggestion or motivation to modify a reference must be found in the prior art.

The present invention is directed to reducing inflammation that results following normal dose photodynamic therapy (PDT). In the claimed methods, tissue that has been treated with normal dose PDT and/or tissue adjacent thereto is exposed to low dose light having a wavelength absorbed by the photosensitizing agent used in the normal dose PDT. Therefore, a *prima facie* case of obviousness requires that the cited reference or the art suggest the use of normal dose PDT and subsequent exposure of the treated area and/or area adjacent thereto to low dose light without administration of additional photosensitizer. Stewart or the general knowledge of the art must provide a motivation to modify the teachings therein to result in the claimed methods and must provide a reasonable expectation of success in modifying the teachings therein. For the reasons discussed below, the cited reference fails to fulfill these requirements for *prima facie* obviousness.

Applicants respectfully submit the cited reference does not suggest the claimed methods because the reference is completely silent on any desirability to modify normal dose PDT as claimed. Stewart discloses low dose PDT treatments for injured tissue to decrease the effects of inflammation arising from the injured tissue.

The Examiner acknowledges that Stewart differs from the claimed invention in “the use of the claimed compounds for prevention or reduction of inflammation associated with photodynamic therapy.” However, the Examiner asserts that it “would have been obvious to a person skilled in the art to employ a compound known for the treatment of inflammation and use of for the treatment of inflammation caused by photodynamic therapy.” Office Action, mailed June 4, 2003, page 2. Applicants disagree with these assertions and respectfully point out that additional differences exist between the cited reference and the claimed invention.

Stewart is silent with regard to the parameters of normal dose PDT and subsequent low dose light treatment and thus, provides no suggestion or motivation to modify the teaching therein to perform normal dose PDT and to follow a normal dose PDT treatment with exposure to low dose light. Also, there is no suggestion in Stewart to consider tissue treated with normal dose PDT as “injured tissue.” No motivation to modify the teachings of Stewart as alleged has been presented in the statement of the rejection. It would not be obvious to modify the teachings of Stewart for use with tissue treated with normal dose PDT unless there is something in Stewart to lead the ordinary artisan to the particular modification. Applicants respectfully submit that there is nothing in Stewart that would provide such direction to the ordinary artisan. The mere description of various “injured tissues” and their causes in Stewart does not necessarily lead to the instantly claimed invention. This follows because Stewart’s broad genus of methods simply does not include any embodiment related to the methods of the instant invention. Moreover, the allegation of a motivation fails to remedy this deficiency by providing evidence of the necessary suggestion or motivation. Without this necessary suggestion or motivation, the instant rejection is an impermissible hindsight reconstruction of the claimed invention using the Stewart reference. *In re Baird* (29 USPQ2d 1550 (Fed. Cir. 1994)) and related holdings in *In re Deuel* (34 USPQ2d 1210 (Fed. Cir. 1995)), *In re Bell* (26 USPQ2d 1529, 1532 (Fed. Cir. 1993)) and *In re Jones* (21 USPQ2d 1941 (Fed Cir. 1992)).

Thus, neither Stewart nor knowledge in the art provides any suggestion or motivation to modify the teaching of Stewart to arrive at the claimed invention.

Finally, Stewart does not provide a reasonable expectation of success of the claimed invention. Since Stewart is silent with regard to the claimed treatment of normal dose PDT and subsequent low dose light exposure to reduce inflammation in the treated tissue, it is impossible for the cited reference to convey a reasonable expectation of success.

Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

The Examiner states that "Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-26 and 29-32 are properly rejected under 35 U.S.C. 103." Final Office Action, page 2. However, since a *prima facie* case of obviousness has not been established, Applicants are not required to provide evidence of an unexpected or unobvious nature of the invention. *In re Bell, Supra*.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 273102011800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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